claims in labeling and promotional materials but on evidence that applies to all manufacturers of cigarettes and smokeless tobacco.

In the case of tobacco products, the evidence of intended use is far broader than labeling for specific products. The evidence regarding the foreseeable pharmacological effects and uses of cigarettes and smokeless tobacco and the actual consumer use of cigarettes and smokeless tobacco for pharmacological effects described in sections II.A. and II.B., above, applies equally to all of the manufacturers and is sufficient to establish that each individual product is "intended to affect the structure or any function of the body," regardless of the identity of the manufacturer. The evidence concerning the statements, actions, research, and knowledge of the manufacturers also supports such a determination. As discussed in sections II.C. and II.D., above, this evidence shows that tobacco manufacturers conducted similar research into nicotine pharmacology; engaged in similar product research and development; use similar methods to manipulate and control nicotine deliveries in commercial products; and jointly belong to associations that have conducted further research into nicotine pharmacology. The evidence thus shows both a widespread understanding within the industry of the pharmacological effects and uses of cigarettes and smokeless tobacco and widespread design of these products to provide pharmacologically active doses of nicotine.

For all of these reasons, it is reasonable and consistent with the public health protection goals of the Act generally and of the tobacco regulations specifically to attribute evidence from all relevant sources—the foreseeability of the pharmacological effects of nicotine for which consumers use cigarettes and smokeless tobacco, the actual consumer use of these products for these effects, the industry's widespread knowledge of

nicotine's pharmacological effects and uses, and the industry's widespread manipulation and control of nicotine—to *all* manufacturers of cigarettes and smokeless tobacco.[1141]

2. Tobacco industry comments argue that some of the statements, research, and actions attributed to particular manufacturers are not relevant to intended use because they are not contemporaneous with the sale of currently marketed products. The Agency disagrees with these comments. One industry comment cites cases involving products

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[1141] The Agency has also determined that processed loose cigarette tobacco, which is used by smokers who roll their own cigarettes, is subject to FDA jurisdiction. One comment contends that the use of "roll-your-own" cigarette tobacco is "fundamentally different from other tobacco products." Consolidated comment of the "Roll-Your-Own" cigarette tobacco manufacturers (Brown & Williamson Tobacco Corp., Robert Burton Associates, Consolidated Cigar Corporation, Douwe Egberts Van Nelle Inc., House of Windsor, Inc., Lane Limited, and Republic Tobacco, L.P.) (Jan. 2, 1996), at 11. *See* AR (Vol. 702 Ref. 1578). The Agency disagrees. Processed loose cigarette tobacco is a cigarette that has not yet been assembled. Roll-your-own cigarettes contain tobacco and are smoked. Like the tobacco used in manufactured cigarettes, loose tobacco contains pharmacologically active doses of nicotine. And, like the tobacco incorporated into commercially manufactured cigarettes, loose tobacco is not simply raw leaves as they are picked from plants in the field. Rather, this tobacco has been cured and treated with many chemicals, and had its moisture content controlled. Consumers obtain separately the components of a cigarette (e.g., processed loose tobacco and special cigarette papers) and then use those components to assemble their own cigarettes. While these homemade products are more crudely manufactured than those produced by cigarette companies, they have the same effect—the smoke from these products is inhaled, and the products deliver nicotine, a drug, for inhalation by the lungs and absorption into the brain. Loose tobacco thus has foreseeable and actual pharmacological effects and uses parallel to manufactured cigarettes, and therefore is "intended to affect the structure or any function of the body" within the meaning of the Act. Further, one of the manufacturers of "roll your own" cigarette tobacco, Brown & Williamson, is also a manufacturer of cigarettes (as well as a manufacturer of smokeless tobacco). Evidence concerning Brown & Williamson's statements, research, and actions, particularly its knowledge that consumers use tobacco products for pharmacological purposes, is discussed in section II.C., above. Because a "roll your own" cigarette is fundamentally the same product as a commercially manufactured cigarette, the evidence discussed in section II.C., above, is also relevant to the manufacturers' intent in producing and selling "roll your own" cigarette tobacco, and is further evidence that processed loose tobacco is subject to FDA jurisdiction.

In addition to the factual and legal arguments supporting the Agency's assertion of jurisdiction over processed loose cigarette tobacco, public health concerns also support including processed loose cigarette tobacco in this proceeding. A "roll-your-own" cigarette poses the same risks as a commercially manufacturered cigarette. The Agency's regulations include restrictions on the access of persons younger than 18 years of age to these products. As discussed in section III.E. of the Final Rule, the public health goals of the Agency's regulations would be thwarted if the regulations were limited to manufactured cigarettes and smokeless tobacco. To exclude processed loose tobacco would provide a simple and obvious way to avoid the restrictions in the regulation. If such an exception existed, cigarettes could be packaged and sold in such a way as to be considered "roll-your-own" products, and young persons would have access to addictive tobacco products, thereby undermining the purpose of the Final Rule.

whose labeling expressly promoted the products as having therapeutic value in treating certain diseases or as affecting the structure or function of the body. *See United States v. Pro-Ag, Inc.*, 796 F. Supp. 1219 (D. Minn. 1991), *aff'd*, 968 F.2d 681 (8th Cir. 1992); *United States v. Neptone*, No. C-83-0864 EFL, CCH ¶ 38,240 (N.D. Cal. Oct. 25, 1983); *United States v. Various Quantities . . . "Instant Alberty Food,"* 83 F. Supp. 882 (D.D.C. 1949). In these cases, however, promotional claims made to consumers were the *sole* basis for establishing intended use. As a result, the courts found that labeling and other promotional material must ordinarily accompany the product and be relied on by consumers purchasing the products. These cases are not controlling, however, where the product has widely recognized pharmacological effects and uses and the government is relying on evidence from other sources—such as evidence of the known and foreseeable pharmacological effects and uses and actual consumer use of the product, and the statements, research, and actions of the manufacturers that demonstrate their intention to facilitate the product's pharmacological effects.

Unlike labeling, which is usually evidence of a manufacturer's current express claims for a product,[1142] the internal documents remain relevant because they evidence an actual intent to affect the structure or function of the body that has not been refuted by more current actions. Indeed, the court in *Alberty Food*, a case cited by the comments, recognized that the mere fact that a manufacturer or shipper stops producing and

[1142] In certain circumstances, such as where consumers continue to rely on previous claims or where discontinued labeling shows a "continuity of purpose" to sell a product as a drug, old labeling can establish intended use. *See, e.g., United States v. Nutrition Service, Inc.*, 227 F. Supp. 375, 386-387 (W.D. Pa. 1964); *United States v. 789 Cases . . . Latex Surgeons' Gloves*, 799 F. Supp. 1275, 1285 (D.P.R. 1992), *aff'd*, 347 F.2d 233 (3d Cir. 1965).

distributing literature that renders a drug misbranded is not an unconditional defense to a charge that the manufacturer or shipper intended to misbrand drugs subject to an enforcement action:

> [i]t is only to the extent that the abandonment of such dissemination creates an inference that the shipper did not intend, when it shipped the drugs in interstate commerce, that they be used for the treatment of the diseases named on the booklets, that the abandonment can be said to be an effective defense. *The government might introduce evidence to show that, notwithstanding such abandonment, it was still the intention of the shipper that the drugs be used for the treatment of the diseases . . .*

83 F. Supp. at 887 (emphasis added).

The court's analysis is pertinent here. The record establishes that the manufacturers have not "abandoned" the design, manufacturing, and marketing practices discussed in the internal documents. To the contrary, the products continue to be marketed and sold in virtually the same manner and form as they were when those documents were produced. *See* section II.C.2.e., above. Thus, the record here supports the Agency's conclusion that the internal documents remain a relevant source of evidence of intended use.

## G. CONSIDERED CUMULATIVELY, THE EVIDENCE OVERWHELMINGLY DEMONSTRATES THAT CIGARETTES AND SMOKELESS TOBACCO ARE INTENDED TO AFFECT THE STRUCTURE AND FUNCTION OF THE BODY

As discussed in sections II.A.-F., the evidence in the record provides several independent bases for the Agency's determination that cigarettes and smokeless tobacco are intended to affect the structure and function of the body. Independently, the evidence in each of these distinct categories of evidence is a sufficient basis for the Agency's conclusion that the manufacturers of cigarettes and smokeless tobacco "intend" their products to affect the structure and function of the body.

In reaching a final determination of the intended use of cigarettes and smokeless tobacco, it is also appropriate for the Agency to consider the objective evidence of intended use as a whole. Considered together, the evidence in each of the different categories of evidence before the Agency—the evidence of the foreseeable pharmacological effects and uses of cigarettes and smokeless tobacco; the evidence of the actual consumer use of cigarettes and smokeless tobacco for pharmacological purposes; and the evidence of the manufacturers' intent as revealed through the manufacturers' statements, research, and actions are highly consistent and support the same conclusion: cigarettes and smokeless tobacco are intended to affect the structure and function of the body. When viewed from the perspective of what a reasonable manufacturer would foresee, how consumers actually use the products, or what is revealed in internal company documents, the evidence in the record demonstrates that cigarettes and smokeless tobacco have intended pharmacological effects and uses. This convergence of independent categories of evidence is highly probative. Taken as a whole, therefore, the evidence in

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the record convincingly establishes that cigarettes and smokeless tobacco are "intended" to affect the structure and function of the body within the meaning of the Act.

## III. CIGARETTES AND SMOKELESS TOBACCO ARE COMBINATION PRODUCTS CONSISTING OF "DRUG" AND "DEVICE" COMPONENTS

As discussed in sections I. and II., above, the Agency has determined that (1) cigarettes and smokeless tobacco "affect the structure or any function of the body," and (2) these effects on the structure and function of the body are "intended" by the manufacturers. These two determinations establish that cigarettes and smokeless tobacco are subject to FDA jurisdiction under the Federal Food, Drug, and Cosmetic Act (the Act). This section explains the basis for the Agency's conclusion that cigarettes and smokeless tobacco are "combination products" consisting of a "drug," nicotine, and "device" components that deliver nicotine to the body.

Under the Act, a product that is intended to affect the structure or function of the body can be a "drug" under section 201(g)(1)(C) or a "device" under section 201(h)(3). The principal difference between a "drug" and a "device" is that a device is "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article" that "does not achieve its primary intended purposes through chemical action within or on the body . . . and . . . is not dependent upon being metabolized for the achievement of its primary intended purposes." Section 201(h)(3). Since the enactment of the Safe Medical Devices Act of 1990, certain products that are intended to affect the structure or function of the body can also be regulated as a "combination product," consisting of a drug and a device. Section 503(g)(1), 21 U.S.C. 353(g)(1). A combination product is a product composed of two regulated components, such as a drug and a device, that "are physically, chemically, or otherwise combined or mixed and produced as a single entity." 21 CFR 3.2(e)(1). Examples of combination

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products include drug delivery systems such as nebulizers, transdermal patches, and prefilled syringes,[1143] as well as prefilled intravenous infusion pumps.

In the Jurisdictional Analysis, the Agency set forth its current view that cigarettes and smokeless tobacco products are combination products under the Act. The Agency explained that "FDA considers device-like products, such as instruments, implements, machines, contrivances, implants, or other similar or related articles . . . , whose primary purpose is delivery of a drug, and that are distributed with a drug product, to be drug delivery systems." 60 FR 41521. The Agency concluded, based on the evidence then available to it, that:

> Cigarettes and smokeless tobacco function in a similar manner in that they contain a drug, nicotine; are used to deliver that drug to the site at which the drug will be absorbed into the body, the mouth or lungs; and after the drug has been delivered, the delivery system, the cigarette butt or smokeless tobacco material, depleted of nicotine, remains and must be disposed of. Only the nicotine delivered by these products achieves its primary intended purpose by chemical action in or on the body.

60 FR 41521–41522. With respect to cigarettes, the Agency further explained that:

> The primary purpose of parts of the cigarette . . . is to effectuate the delivery of a carefully controlled amount of nicotine to a site in the human body where it can be absorbed. The drug, nicotine, is generally contained within the treated rolled tobacco. The delivery system, the nicotine-containing cigarette, must be lit to have its intended effect on the structure or function of the body, and, once lit and used, is discarded. When lit, the cigarette produces nicotine-containing smoke, which is inhaled by the consumer and when absorbed into the lungs, yields on average approximately 1.0 mg of nicotine.

60 FR 41522. With respect to smokeless tobacco, the Agency further explained that:

> Smokeless tobacco products function like infusion devices or transdermal patches that deliver continuous amounts of nicotine to the cheek tissue for

[1143] Intercenter Agreement between the Center for Drug Evaluation and Research and the Center for Devices and Radiological Health (Oct. 31, 1991), at 6. See AR (Vol. 30 Ref. 289).

> absorption into the bloodstream. The device element of smokeless products is the tobacco, which contains the nicotine but is not intended to be consumed. Instead, in normal use, most of the tobacco in the product is not absorbed by the user and is removed from the mouth after absorption of the nicotine through the cheek tissue.
>
> The primary purpose of the tobacco is to provide a palpable vehicle that allows nicotine to be extracted from the tobacco by the user's saliva so that it may be absorbed into the body.

60 FR 41522–41523.

After carefully considering the evidence in the administrative record and the comments received, the Agency reaffirms these findings and concludes that cigarettes and smokeless tobacco are combination products that contain a "drug" and a "device."

### A. NICOTINE IN CIGARETTES AND SMOKELESS TOBACCO IS A DRUG

For the reasons set forth in sections I. and II., above, the Agency concludes that the nicotine in cigarettes and smokeless tobacco is a "drug" under section 201(g)(1)(C). The nicotine in these products "affect[s] the structure or any function of the body" by sustaining addiction, by producing other important pharmacological effects on the central nervous system, including tranquilizing and stimulant effects, and by controlling weight. *See* section I., above. These effects of the nicotine in cigarettes and smokeless tobacco are "intended" by the manufacturers. *See* section II., above. Therefore, the nicotine in cigarettes and smokeless tobacco meets the statutory definition of a "drug" under section 201(g)(1)(C).

## B. CIGARETTES AND SMOKELESS TOBACCO CONTAIN DELIVERY DEVICES AND ARE COMBINATION PRODUCTS UNDER THE ACT

Cigarettes and smokeless tobacco are not simply packaged nicotine. As discussed below, the rest of the cigarette or smokeless tobacco product includes a delivery device that delivers a controlled amount of nicotine to the body. This combination of the drug nicotine and a delivery device makes these products "combination products."

Under the Act, a device is:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended to affect the structure or any function of the body of man . . . and which does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Section 201(h)(3). This definition was intended to bring within the reach of the statute articles that are intended to affect the structure or function of the body, but are physically distinguishable from drugs, which in general are substances in liquid, powder, or other drug dosage form that are ingested, injected, rubbed, or otherwise absorbed into the body. The definition establishes a four-part test for a device. First, the article must be "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article." Second, the article must be "intended to affect the structure or any function of the body." Third, the article must not "achieve its primary intended purposes through chemical action within or on the body of man." And fourth, the article must not be "dependent upon being metabolized for the achievement of its primary intended purposes." Both cigarettes and smokeless tobacco contain a delivery device that meets these four criteria.